

# The efficacy and safety of new moisturizing cream for dry skin condition and itch relief

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<b>Registration date</b> 20/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/05/2014	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to establish the effectiveness and safety data of a new moisturizing cream, which is approved by the Korean Food and Drug Administration for dry skin conditions and itch relief. The results of this study will be used to present the evidence for advertising/display allowances to comply with the recently amended Cosmetic Act for advertisement.

### Who can participate?

We will recruit 66 healthy male and female, aged 20 to 65 years diagnosed with dry skin conditions.

### What does the study involve?

Participants will be randomly allocated to either receive new moisturizing cream or placebo (dummy) cream for four weeks. Each participant will be examined for signs and symptoms before and after using the cream. Skin hydration, sebum (oily secretion) content and transepidermal water loss (constitutive loss of water from the skin surface) will be assessed. Participants will also be asked to fill out a health-related quality of life questionnaire. Safety will be assessed by blood tests, urine analysis, pregnancy test, and vital signs.

### What are the possible benefits and risks of participating?

The results will help to evaluate the effectiveness and safety of new moisturizing cream for dry skin condition and itch relief. It can therefore be considered a suitable preparation that may be used effectively by most patients with dry skin conditions.

### Where is the study run from?

This study has been set up by the Wonkwang University Oriental Medical Center in collaboration with Coreana Cosmetics (Co., Ltd.).

### When is study starting and how long is it expected to run for?

The study started in April 2013 and is expected to run till October 2013.

### Who is funding the study?

Korea Health Industry Development Institute

Who is the main contact?  
Professor Kim, NamKwen  
drkim@wonkwang.ac.kr

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Namkwen Kim

**Contact details**  
Wonkwang University Oriental Medical Center  
1126-1 Sanbon-dong  
Gunpo  
Korea, South  
435-040  
+82-31-390-2671  
drkim@wonkwang.ac.kr

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
A10301712131160101

## Study information

**Scientific Title**  
The efficacy and safety of new moisturizing cream for dry skin condition and itch relief: a randomized, double-blind, placebo-controlled trial

**Study objectives**  
This study is aimed at proving the efficacy and safety data of a new moisturizing cream, which is approved by the Korean Food and Drug Administration, for dry skin condition and itch relief.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Wonkwang University Oriental Medical Centre Ethics Committee approved on 3rd April 2013

**Study design**

Randomized double blind two arm placebo controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Dry skin condition in healthy volunteers

**Interventions**

New moisturizing cream or placebo cream will be applied to the affected areas of skin, on the inner surface of left forearm and right side of the face after washing, twice daily (morning and evening), for four weeks.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Efficacy: Measured Day 1, Day 15 and Day 29

1. Measurement of skin hydration (Corneometer)
2. Measurement of sebum content (Sebumeter)
3. Measurement of transepidermal water loss (Tewameter)

**Secondary outcome measures**

Efficacy:

1. Measurement of stratum corneum content (Corneofix). Measured on day 1, day 15 and day 29
2. Visual analogue scale (VAS)-xerosis, VAS-itching. Measured on day 1, day 15 and day 29
3. Dermatology Life Quality Index (DLQI), Euro-Qol 5-Dimension (EQ-5D) and Health Utilities Index Mark 3 (HUI-3). Measured on day 1 and day 29

Safety:

1. Vital signs- measured during screening, day 1, day 15 and day 29
2. Blood chemistry- measured during screening and day 29
3. Complete blood cell count, erythrocyte sedimentation rate- measured during screening and day 29
4. Urine analysis- measured during screening and day 29

5. Pregnancy test- measured during screening
6. Picture on the skin lesion and adverse events evaluation- measured on day 1, day 15 and day 29

**Overall study start date**

10/04/2013

**Completion date**

31/10/2013

## Eligibility

**Key inclusion criteria**

1. Volunteer individuals aged 20 to 65 years, either sex
2. Written and informed consent
3. Healthy volunteers without skin disease or any other diseases (acute or chronic)
4. Diagnosed with dry skin condition by the doctor (Korean Medicine), or presented with itching or dry skin condition
5. Available for follow-up observations during clinical trial period

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

66

**Key exclusion criteria**

1. Pregnancy, lactating, or planned pregnancy
2. People who use external application containing steroids for the treatment of skin disease more than one month
3. Participated in the same trial within six months from the interview
4. People with hypersensitive skin
5. Skin abnormalities such as severe acne, erythema, telangiectasia on the test site
6. Used the same or similar cosmetic (or pharmaceutical) on the test site within three months from the interview
7. Have peeling of skin or wrinkles removed within six months from the interview
8. Other unsuitable reasons for clinical trial based on the discretion of the investigator

**Date of first enrolment**

10/04/2013

**Date of final enrolment**

31/10/2013

# Locations

## Countries of recruitment

Korea, South

## Study participating centre

Wonkwang University Oriental Medical Center

Gunpo

Korea, South

435-040

# Sponsor information

## Organisation

Korea Health Industry Development Institute (KHIDI) (South Korea)

## Sponsor details

187 Osongsaengmyeong2(i)-ro

Gangoe-myeon

Cheongwon-gun, Chungcheongbukdo

Korea, South

363-951

+82-43-713-8752

shouter0@khidi.or.kr

## Sponsor type

Research organisation

## Website

<http://www.khidi.or.kr/eng/index.jsp>

## ROR

<https://ror.org/00fdzyk40>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Korea Health Industry Development Institute (KHIDI) (South Korea)

**Alternative Name(s)**

KHIDI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Korea, South

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	25/11/2013		Yes	No